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October 27, 2014

The Honorable Gregory M. Sleet
United States District Court
844 North King Street
Wilmington, DE 19801

VIA ELECTRONIC FILING

Re: *Bayer Intellectual Property GmbH, et al. v. Warner Chilcott Company, LLC, et al.*,
C.A. No. 12-1032-GMS

Dear Judge Sleet:

The parties submit this joint letter in anticipation of the status conference scheduled for October 31. See Oral Order of Oct. 15, 2014. The parties' respective positions are set forth below.

1. Warner Chilcott respectfully requests permission to file, without further expert discovery, a summary judgment motion seeking a declaration that the '940 patent is indefinite, in light of the Court's October 9 claim construction order. (D.I. 120.) In that order, this Court noted that its inability to construe claim terms in the '940 patent "may unavoidably present an indefinite[ness] issue that will need to be addressed at summary judgment." (Order at 7.)

Warner Chilcott believes immediate summary judgment briefing is appropriate because (1) the test for indefiniteness is now satisfied as a matter of law, and a motion recognizing this fact would dispose of all issues in the case; and (2) conducting further expert discovery would be wasteful and raise vexing questions as to how the experts should proceed.

That the Court was unable to construe claim terms in *Markman* proceedings in light of the specification and prosecution history, from the standpoint of a person of ordinary skill, by definition means that the asserted claims are indefinite. *Nautilus, Inc. v. Biosig.*, 134 S. Ct. 2120, 2124 (2014). Claims not amenable to construction are indefinite, *Halliburton Energy v. M-I LLC*, 514 F.3d 1244, 1251 (Fed. Cir. 2008), a finding courts routinely make when they are unable to ascertain claim scope in *Markman* proceedings. *E.g., Interval Licensing v. AOL*, 766 F.3d 1364, 1368-1373 (Fed. Cir. 2014); *Triton Tech v. Nintendo*, 753 F.3d 1375, 1377-1378 (Fed. Cir. 2014).

Permitting expert discovery to move forward would also be wasteful. Additional expert testimony cannot make indefinite claims definite.¹ *See, e.g., Interval Licensing*, 766 F.3d at 1370 n.6. And Bayer has *already* submitted expert testimony and other extrinsic evidence in support of its proposed constructions (D.I. 67-68), which the Court has already rejected. (D.I. 120, at 7.) Moreover, without claim constructions, it would not be *possible* for the experts to fully analyze infringement or interference. *See* D.I. 120, at 7; *Medichem, S.A. v. Rolabo*, 353 F.3d 928, 932-33

¹ In stark contrast to what it now argues, Bayer previously told this Court that it was not "necessary" to consider expert testimony (D.I. 67, n.2), and that the meaning of the disputed terms "is clear from the text of the claim itself." (D.I. 84, at 17.)

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(Fed. Cir. 2003) (first step in interference analysis is to construe the claims). Bayer apparently seeks to continue the claim construction process despite the fact that the Court has already issued a claim construction order, which is now law of the case. The issue at this point is not what the “whereby” clause means—the Court has already determined that its meaning cannot be ascertained—but what the legal effect is of that determination: that issue is ripe for adjudication now, either by summary judgment or by Bayer agreeing, as it should, to entry of judgment, after which it can take an appeal.

2. Bayer respectfully requests that the Court deny Warner Chilcott’s request to amend the scheduling order. Bayer submits that the Court should not rule on indefiniteness without first permitting Bayer to develop expert evidence on the understanding of a person of skill in the art.

A patent is indefinite only “if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc.*, 134 S. Ct. at 2124. Additional factual development is necessary regarding this inquiry, including the need for extrinsic evidence and expert testimony. *See Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1120 (Fed. Cir. 2002). After *Nautilus*, “the definiteness inquiry turns on the understanding of a skilled artisan at the time of the patent application, not that of a court viewing matters post hoc.” *Nautilus*, 134 S. Ct. at 2130. Such evidence and testimony will be helpful in defining whether the claims at issue would delineate the scope of what is claimed with “reasonable certainty” to “those skilled in the art” at the time that the patent application was filed. *Id.*; *see also Source Search Techs., LLC v. LendingTree, LLC*, 588 F.3d 1063, 1076 (Fed. Cir. 2009); *Mycone Dental Supply Co. v. Creative Nail Design*, CIV.A. 11-4380 JBS, 2014 WL 3362364, *4 (D.N.J. July 9, 2014). For example, Warner Chilcott’s own expert in other litigation has been able to make the same conclusions about Lo Loestrin that are set forth in the “whereby” clause, saying Lo Loestrin has a “low incidence of side effects,” a “low amount of total bleeding per cycle,” and “acceptable suppression of follicular development and cycle control.”

Bayer submits that the Court’s inability to construe certain claims in the patent as part of claim construction does not mandate that the patent is indefinite, nor does it mandate that summary judgment should be granted prior to the development of a full record that includes properly admissible expert testimony. The standard for indefiniteness is proof by clear and convincing evidence, a more exacting standard than what governs claim construction and an inquiry that includes broader categories of evidence (including expert testimony) than claim construction. *Int’l Dev. LLC v. Richmond*, CIV.A. 09-2495 GEB, 2010 WL 4703779 (D.N.J. Nov. 12, 2010) (declining to rule on indefiniteness during *Markman* based on factors that “militate against determining indefiniteness prior to the end of all discovery”); *Alcon Research, Ltd. v. Barr Labs. Inc.*, 09-CV-0318-LDD, 2011 WL 3901878, at *17 (D. Del. Sept. 6, 2011) (“[W]e decline to adopt a construction other than that which is stated in the patents, and we defer further consideration of the term until the appropriate time at trial.”).

Bayer believes that expert discovery can proceed without undue burden. Expert reports were originally due on October 17, 2014. As a result, the parties have already incurred much of the cost of expert testimony. Proceeding with all expert discovery makes it possible to maintain the original trial date. If the Court denies Warner Chilcott’s request or its motion, the parties will be prepared to proceed to trial or a hearing on Bayer’s interference claim without an additional expert-discovery period.

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Respectfully,

/s/ Steven J. Balick

Steven J. Balick (#2114)

SJB/nlm

cc: All Counsel of Record